UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,381	02/06/2002	Mark A. Goldsmith	GLAD001CON	2681

24353 7590 07/27/2004

BOZICEVIC, FIELD & FRANCIS LLP
200 MIDDLEFIELD RD
SUITE 200
MENLO PARK, CA 94025

EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,381	GOLDSMITH ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/5/04 .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 28,30-37,39,50-54 is/are pending in the application.

4a) Of the above claim(s) 32,50 and 52 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 28,30,31,33-37,39,51,53 and 54 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 06 February 2002 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment, terminal disclaimer, and the response filed 5/5/04 have been entered. Claims 29, 38, and 49 have been canceled. Claims 28 and 53 have been amended. It is noted that the amendments to claims do not comply with the Revised Amendment Practice of 37 CFR 1.121 (See OG Notice 23 September 2003). Specifically, claims 32, 50, and 52 should have been marked as "withdrawn" in the listing of the claims. Appropriate correction is required in the future submission. Claims 28, 30, 31, 33-37, 39, 51, 53, and 54 are under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in 5/4/04 response would be addressed to the extent that they apply to current rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The previous rejection of Claims 28-31, 33-39, 51, 53, and 54 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 11, 13 of U.S. Patent No. 6,372,956, is withdrawn in view of the terminal disclaimer.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The prior rejection of Claims 28-31, 33-39, 51, 53, and 54 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in view of claim amendment.

Claims 28, 30, 31, 33-37, 39, 51, 53, and 54 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Amended claims are drawn to a transgenic rat whose genome comprises three stably integrated transgenic nucleotide sequences, preferably CD4, CCR5, and a subunit of p-TEFb comprising cyclin T, wherein the three transgenes are constructed into one vector and operably linked to a lymphocyte promoter, which results in the transgenes to be preferentially expressed in T-cells/macrophages.

As an initial matter, it is noted that since the promoter is now lymphocyte-specific, the claims do not appear to be enabled for expressing the transgenes in macrophage, and the specification fails to teach otherwise.

Applicants then state that the Office action appears to recognize that transgenic animals may be produced provided certain specificity is provided with respect to the transgens being included there is an acceptable degree of predictability that is now believed to have been met.

In response, although the amended claims limit the third transgene to a subunit of p-TEFb comprising cyclin T, the claims encompass numerous rats with different phenotype combinations, i.e. the combination of a hCD4 receptor, anyone of a group of chemokine receptor such as those recited in claim 33, and a subunit of p-TEFb comprising cyclin T. The Office action acknowledges the technique for making transgenic animals has become routine in the relevant art, but the resulting genotype and phenotype varies significantly depending on the genes being manipulated, and the animals being used for reasons taught by the cited artisans (pages 8-10 of the Office action mailed 1/8/04). The specification fails to provide an enabling disclosure because it fails to teach how such rat is made, and it fails to disclose the feasibility and reproducibility of a tri-transgenic rat whose genome comprises three homogenous transgenes thus has the desired phenotype. Example 4 of the specification teaches that lines of rats with two homogenous transgenes were made with the vectors of figures 2-5, but the method steps of making the rats are missing in the specification. Although claims 53 and 54 provided the method steps of making the rats, the claims do not

appear to be enabled because the method steps require use of ES cells for blastocyst implant. However, as indicated in the previous Office action, the art of record indicates that the purposed ES cells have not been isolated in rat species (pages 12-13 of the Office action mailed 1/8/04), hence the claims lack support from the specification or art of record. Assuming then the rats were made with somatic cell cloning, the specification fails to teach how to overcome the art known hurdles in somatic cloning as taught by the cited artisans (pages 10-11 of the Office action mailed 1/8/04), and whether the claimed rat could be readily made without undue experimentation. Under the circumstance, a deposited embryo of the claimed rat that is in compliance with Budapest Treaty may be made to obviate the non-enablement rejection; however it does not apply to the instant case, because the claimed tri-transgene rat has not been made. In view of these considerations, the specification fails to provide an enabling disclosure to allow the claimed product readily available to the public, and thus, fails to provide an enabling disclosure for what is now claimed.

Further, the response fails to address the issue that a rat with a heterozygous allele for anyone of the three transgenes would not have a phenotype, thus indistinguishable from a wild-type rat.

Accordingly, for reasons of record and those set forth above, the specification fails to meet the statutory enablement requirement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites the limitation "the polypeptide" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Objections

Claim 35 is objected to because it depends from a canceled claim.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JANICE LI
PATENT EXAMINER

Q. Janice Li
Patent Examiner
Art Unit 1632

QJL
July 16, 2004

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER